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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,725	11/19/2003	Nicholas Mazarakis	674523-2017.1	8892

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EXAMINER	
LIETO, LOUIS D	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,725	MAZARAKIS ET AL.	
	Examiner	Art Unit	
	Louis D. Lieto	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *35,39,43 and 45-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34,36-38,40-42 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/12/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to the Restriction requirement was received on 4/28/2006. Claims 1-50 are pending in the instant application. Applicant's election with traverse of Group I, claims 1, 31, drawn to a method of treating a motor neuron disease in a patient in need thereof, comprising delivering a NOI, wherein the NOI encodes a neurotrophic product, such as SMN-1, GDNF, IGF-1 or VEGF, is acknowledged.

It is noted that the prior restriction requirement was based on claims 1-31 submitted on 11/19/03, rather than the claims 1-50 amended on 4/22/05. Upon review the claims have been regrouped as follows: Group I, claims 1-34,36-38,40-42, and 44; Group II, claims 1-35,37-39, and 41-43; and Group III, claims 1, and 45-50 drawn to a method of treating a motor neuron disease in a patient in need thereof, comprising delivering a NOI, wherein the NOI encodes an interfering RNA.

Claims 35,39, 43 and 45-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/28/2006.

Response to Arguments

Applicant's election with traverse of Group I in the reply filed on 4/28/2006 is acknowledged. Applicant argues that the inventions are neither independent or distinct, and that there would be no undue search burden on the examiner. However, the invention of group I is drawn to neurotrophic proteins, which have patentably distinct structures and functions from the

anti-apoptotic proteins of group II as well as the interfering RNA of group III. Further, the search of a neurotrophic protein, a anti-apoptotic protein, and a small interfering RNA are not co-extensive. Finally, the inventions of groups I -III have a separate status in the art as shown by their different classifications As such, it would be burdensome to search the inventions of groups I-III together.

Claims 1-34,36-38,40-42, and 44 are under consideration.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in England on 10/04/2002. It is noted, however, that applicant has not filed a certified copy of the UK 0223076.1 application as required by 35 U.S.C. 119(b).

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in England on 12/04/2002. It is noted, however, that applicant has not filed a certified copy of the UK 0228314.1application as required by 35 U.S.C. 119(b).

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in England on 8/04/2003. It is noted, however, that applicant has not filed a certified copy of the UK 0318213.6 application as required by 35 U.S.C. 119(b).

It is noted that these applications were not filed in the parent application 10/716,725.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 10, 11 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of delivering a lentiviral vector psuedotyped with a mutant, variant, homologue or fragment of a rabies G protein, comprising an NOI, such as GDNF to a target site. The claims encompass a genus of rabies G proteins, mutants, variants, homologues or fragments.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing characteristics of the genus. The claimed genus contemplated in the specification encompasses any rabies G protein mutant containing one or more addition, substitution, or deletion from the wild-type rabies G protein; any rabies G protein variant including any naturally occurring polypeptide which differs from the wild-type rabies G protein sequence, from the same or different strain; any rabies G protein homologue with at least 75, 85 or 90% identity to the wild-type rabies G protein; and any rabies G protein fragment including any fraction of the wild-type rabies G protein, including large continuous sections or a plurality of small sections, and fusion proteins. The claimed genus of vector systems encompasses a vast number of different vectors and combinations thereof (Specification pgs. 34-42).

The factors to be considered when assessing possession of the claimed invention include disclosure of complete or partial structure, physical and/ or chemical properties, functional

characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

In the instant case, the rabies G protein contemplated in the specification includes any protein with at least one amino acid in common with the wild-type rabies G protein, any fragment down to 1 amino acid or a series of such single amino acids, or an undefined part of any mutant, variant, homologue or fragment of the wild-type rabies G protein. The specification does not require that any functional domain or structural motif be conserved amongst this vast array of proteins. Accordingly, in the absence of sufficient recitation of a distinguishing identifying characteristic, the specification does not provide adequate written description of the claimed genus of rabies G proteins, mutants, variants, homologues or fragments.

The Revised Interim Guidelines state, "when there is substantial variation with the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus" (Column 2, page 71436, or the Revised Interim Guidelines for Written Description). Case law concurs, stating, "simply describing large genus of compounds is not sufficient to satisfy written description requirement as to particular species or sub-genus" *Fujikawa v. Wattanasin*, 39 USPQ2d 1895 (CA FC 1996). Furthermore, *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath

at page 1116). Thus, the specification does not meet the written description provision of 35 U.S.C. 112, first paragraph, for a genus of at least a part of a rabies G proteins, mutants, variants, homologues or fragments. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision.

Claims 1-34,36-38,40-42, and 44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of delivering a NOI to a target site, comprising the administration of an EIAV vector (pONY8z) pseudotyped with a rabies G protein selected from ERAwt, ERAsm, ERAdm, or CVS, comprising a NOI to a target site, does not reasonably provide enablement for a method of treating any motor neuron disease in a patient, a method of delivering a NOI or a method of expressing a NOI, comprising administration of any lentivirus psuedotyped with a rabies G protein, such as a rabies G protein mutant, variant, homologue or fragment, comprising any NOI, such as SMN-1, GDNF, IGF-1 or VEGF. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claims encompass a method of treating any motor neuron disease in a patient, a method of delivering a NOI or a method of expressing a NOI, comprising administration of any lentivirus psuedotyped with a rabies G protein, such as a rabies G protein mutant, variant, homologue or fragment, comprising any NOI, such as SMN-1, GDNF, IGF-1 or VEGF. The specification contemplates treating any motor neuron disease, such as Parkinson's disease (PD), motor neuron diseases including amyotrophic lateral sclerosis (ALS or Lou Gehrig's Disease)

and Huntington's disease; Alzheimer's disease; Spinal Muscle Atrophy and Lysosomal Storage Diseases.

The claims are drawn to any lentiviral system comprising any part of rabies G protein or mutant, variant, homologue or fragment thereof. However, the specification only provides working examples that show the administration of a nucleic acid encoding lacZ via an EIAV vector (pONY8z) pseudotyped with a rabies G protein (Specification pgs. 65-86) to rats. The specification does not provide any guidance on methods of treating any motor neuron disease or using any other specific lentiviral vector.

It is noted that applicant's elected invention was drawn to SMN-1, GDNF, IGF-1 or VEGF as the proteins encoded by the NOI, However applicant has not provided any information on the nucleic acid sequence of the NOI encoding SMN-1, GDNF, IGF-1 or VEGF, or any evidence that expressing SMN-1, GDNF, IGF-1 or VEGF in any motor neuron can treat any motor neuron disease. Further, Amgen removed their drug Liatermin, a peptide GDNF drug, from clinical trials for the treatment of Parkinson's Disease (PD) (Lang et al. (2004) E-move. Article ID=762, pg. 1, pgph 2). The GDNF was removed from clinical trials because the results indicated that out of 34 PD patients in a double blind study, receiving GDNF or a placebo, no differences were observed (Lang et al. pg. 1, pgph 4). Therefore the artisan skilled in the art would not predict that delivery of a nucleic acid encoding GDNF to motor neurons, or any other cell in the CNS by any means would have any therapeutic effect on patients with PD, when a GDNF peptide did not. Further the specification fails to provide any guidance on how much GDNF must be expressed and for what duration, in order to treat PD. The specification also lacks

any guidance on any regulatory elements operably linked to the nucleic acid encoding GDNF, such as whether the promoter is to be constitutive or inducible.

It is emphasized that the specification, except for general statements and description, does not provide any specific guidance on how to treat any motor neuron disease, such as PD. Specifically there is no guidance on how to make an agent with the intended properties and to use it for the intended purpose, e.g. therapeutic effect.

Verma et al. states that in the past, the Achilles heel of gene therapy was gene delivery, and that, most of the approaches suffer from poor efficiency of delivery and transient expression of the gene {Verma et al. (1997) Nature, Vol. 389, page 239, column 3, paragraph 2}. These issues remain as current problems in the field of gene therapy. Pfeifer and Verma state that even "though gene therapy holds great promise for the achievement of this task, the transfer of genetic material into higher organisms still remains an enormous technical challenge { Pfeifer and Verma (2001) Annu. Rev. Genomics. Hum. Genet. 2:177-211; pg. 177, pgph 1}. Johnson-Saliba et al. concurs stating that "although thousands of patients have been involved in clinical trials for gene therapy, using hundreds of different protocols, true success has been limited. A major limitation of gene therapy approaches, especially when non-viral vectors are used, is the poor efficiency of DNA delivery." {Johnson-Saliba et al. (2001) Curr. Drug. Targets 2:371-99; Abstract}. Such problems with delivery continue to plague the field of gene therapy. Shoji et al. has characterized the current state of the art as the "tragic failure of gene therapy" because of poor delivery of gene based-medicines due to the lack of an appropriate vector that "fulfills the necessary requirements, including high transfection efficiency, non-toxicity, non-pathogenicity,

non-immunogenicity, [and] non-tumorgenicity." {Shoji et al. (2004) Current Pharmaceutical Design 10 :785-796}.

The imputed novelty of the vector system is the pseudotyping of the lentiviral vector with a rabies G protein. However, the specification teaches that side by side comparisons of EIAV vectors pseudotyped with VSVG or rabies G protein showed the same overall transduction efficiencies of substantia nigra at the highest dosage levels(Specification pg. 69). While the VSVG pseudotyped EIAV vector had nearly double the efficiency of the rabies G protein pseudotyped EIAV vector at the middle dosage level (Specification pg. 64, Table 4). Thus applicant's own data indicates that the presence of a rabies G protein in a vector has little or no effect on the transduction efficiency of neurons *in vivo*. Further, while the results observed in rats after intercranial injection of the vectors into a rats brain indicate that the rabies G protein pseudotyped EIAV vector transferred the gene to a larger area of tissue than the VSVG pseudotyped EIAV vector, the specification does not relate this difference to any therapeutic effect for the treatment of any motor neuron disease (specification pg. 67, lines 1-10). For example PD is characterized by the degeneration of the pigmented neuromelanin bearing cells of the zona compacta of the substantia nigra {Sethi et al. (2002) Curr. Op. Nuer. 15:457-460}. However, the specification does not provide any guidance on the transduction of the pigmented neuromelanin bearing cells of the zona compacta of the substantia nigra to the deliver a therapeutic NOI for treatment of PD.

The specification does not provide any evidence that: 1) the rabies G protein pseudotyped EIAV vector can transfect these neurons in a human with any motor neuron disease, or in an animal model; 2) that a nucleic acid encoding GDNF can be expressed in these cells; and

3) that the expression of GDNF in these cells can treat said motor neuron disease. Finally, while the specification shows that rabies G protein pseudotyped EIAV vector can transfer a nucleic acid encoding lacZ to 27% FG-back labeled motor neurons via intramuscular injection (Specification pg. 75, lines 1-12), this is not correlated with any transduction of any neurons for treatment of any motor neuron disease, such as ALS, SMA or stroke.

The specification fails to provide a disclosure that would allow enable a skilled practitioner to practice the claimed invention commensurate in scope with the claims. The specification does not provide any evidence showing that any NOI, such as SMN-1, GDNF, IGF-1 or VEGF can be delivered by any lentivirus comprising any part of rabies G protein or mutant, variant, homologue or fragment thereof in order to treat any motor neuron disease. Further, the art teaches that a GDNF peptide drug is not useful to treat PD. The only lentivirus containing a rabies G protein, shown in the specification to successfully transfect neurons *in vivo* is the rabies G protein pseudotyped EIAV vector, and it did so with an efficiency equal to or less than a VSVG pseudotyped EIAV vector. Thus it is not clear what advantage the rabies G vector offers over the VSVG vector. The specification does not provide any evidence that even if the target site in the central nervous system was successfully transduced with the claimed vector system, and the NOI was expressed it would have any therapeutic effect on the treatment of any motor neuron disease, such as ALS, SMA or stroke. Therefore, the skilled practitioner would be unable to practice the claimed invention, except as a method of delivering a NOI to a target site, comprising the administration of an EIAV vector (pONY8z) pseudotyped with a rabies G protein selected from ERAwt, ERAsm, ERAdm, or CVS, comprising a NOI to a target site, without undue and extensive experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 11, 20 and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Reiser et al. {Reiser et al. (6.2000) Gene Therapy 7 :910-913}.

Reiser et al. provides guidance on the use of HIV-1 vectors pseudotyped with rabies G protein for use in gene transfer (Abstract). Wherein the vectors can be used for gene delivery *in vivo* to cells of the central nervous system, muscle or liver (pg. 910, col. 1, pgph 1). Thus, by teaching all the limitations of the claims as written, Reiser et al. anticipates the instant invention as claimed.

Claims 1-5, 7,8,10-14,17,18,20-24,27,28,30,32,34,38,42 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No 6,818,209 (11.16.2004), given priority to (7.17.1998) hereafter referred to as Mitrophanous et al.

Mitrophanous et al. provides guidance on: "a retroviral vector delivery system capable of transducing target cells, wherein the retroviral vector delivery system comprises a first nucleotide sequence encoding at least part of a rabies G protein or mutant, derivative or fragment thereof; and one or more other nucleotide sequences that ensure transduction of a target neuronal cell by the retroviral vector delivery system; wherein the first nucleotide sequence is heterologous with respect to at least one of the other nucleotide sequences; and wherein the rabies G protein or mutant, variant, or fragment thereof pseudotypes the retroviral vector delivery system whereby the retroviral vector delivery system selectively transduces neuronal cells at a higher transduction efficiency than neuronal cells transduced with a retroviral vector delivery system pseudotyped with a VSV-G protein." (Claim 1, 21). Wherein the preferred retroviral vector is a lentiviral vector such as EIAV (Claim 12; Col 12). Wherein the viral vector encodes a therapeutic NOI, such as genes encoding tumor suppressor proteins, cytokines, anti-viral proteins, immunomodulatory molecules, antibodies, engineered immunoglobulin-like molecules, fusion proteins, hormones, membrane proteins, vasoactive proteins or peptides, growth factors, ribozymes, enzymes, prodrugs, such as pro-drug activating enzymes, cytotoxic agents, and enzyme inhibitors (Col 11). Wherein the target site is neuronal (Claim 21) and said vector system may be used to target astrocytes, or glial cells (col. 11, lines 34-39) and to treat stroke or neurodegenerative diseases such as Parkinson's disease (col. 11, lines 25-33). Finally, Mitrophanous et al. teaches that the vector system can be administered intracavernosally, intravenously, intramuscularly or subcutaneously (Col. 13, lines 59-67). It is inherent that the NOI will diffuse from a distal administration site to the target site. Thus, by

teaching all of the limitations of the claims as written, Mitrophanous et al. anticipates the instant invention as claimed.

Claims 1-5, 7,8,10-14,17,18,20-24,27,28,30,32,34,38,42 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

US Patent No 6,818,209 (11.16.2004), given priority to (7.17.1998) hereafter referred to as Mitrophanous et al. shares inventorship with the instant application. Specifically, Susan M. Kingsman is present on both patents. However, the instant application has no recorded assignee and lists Mimoun Azzouz and Nicholas Mazarakis, who are not listed as inventors on US Patent No 6,818,209. Further, US Patent No 6,818,209 was assigned to Oxford Biomedica (UK) Limited and lists Kyralacos Mitrophanous, Deva Patil, Alan J. Kingsman and Fiona Ellard, who are not listed as inventors on the instant application. Therefore US Patent No 6,818,209 is by another.

Mitrophanous et al. provides guidance on: "a retroviral vector delivery system capable of transducing target cells, wherein the retroviral vector delivery system comprises a first nucleotide sequence encoding at least part of a rabies G protein or mutant, derivative or fragment thereof; and one or more other nucleotide sequences that ensure transduction of a target neuronal cell by the retroviral vector delivery system; wherein the first nucleotide sequence is heterologous with respect to at least one of the other nucleotide sequences; and wherein the rabies G protein or mutant, variant, or fragment thereof pseudotypes the retroviral vector delivery system whereby the retroviral vector delivery system selectively transduces neuronal cells at a higher transduction efficiency than neuronal cells transduced with a retroviral

vector delivery system pseudotyped with a VSV-G protein." (Claim 1, 21). Wherein the preferred retroviral vector is a lentiviral vector such as EIAV (Claim 12; Col 12). Wherein the viral vector encodes a therapeutic NOI, such as genes encoding tumor suppressor proteins, cytokines, anti-viral proteins, immunomodulatory molecules, antibodies, engineered immunoglobulin-like molecules, fusion proteins, hormones, membrane proteins, vasoactive proteins or peptides, growth factors, ribozymes, enzymes, prodrugs, such as pro-drug activating enzymes, cytotoxic agents, and enzyme inhibitors (Col 11). Wherein the target site is neuronal (Claim 21) and said vector system may be used to target astrocytes, or glial cells (col. 11, lines 34-39) and to treat stroke or neurodegenerative diseases such as Parkinson's disease (col. 11, lines 25-33). Finally, Mitrophanous et al. teaches that the vector system can be administered intracavernosally, intravenously, intramuscularly or subcutaneously (Col. 13, lines 59-67). It is inherent that the NOI will diffuse from a distal administration site to the target site. Thus, by teaching all of the limitations of the claims as written, Mitrophanous et al. anticipates the instant invention as claimed.

Claims1-5,7-15,17-15,27-32,34,36,38,40,42, and 44 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. Co-pending US patent application 2004/0266715 (12.30.2004) shares inventorship with the instant application. Specifically, Nicholas Mazarakis is present on both patents. However, the instant application has no recorded assignee and lists Mimoun Azzouz and Susan Mary Kingsman, who are not listed as inventors on application 2004/0266715. Further, application 2004/0266715 was assigned to Oxford Biomedica (UK) Limited and lists Liang Fong Wong, Alan Kingsman, Stephen

McMahon and Malcolm Maden, who are not listed as inventors on the instant application. Therefore application 2004/0266715 is by another.

Claims 1-7 of co-pending application 2004/0266715 are drawn to a method for treating nerve injury in a mammal in need of such treatment, comprising administering a lentiviral vector pseudotyped with a rabies G protein, wherein the NOI encodes the RARβ2 protein. Further, 2004/0266715 provides guidance on the administration of an EIAV vector pseudotyped with a rabies protein encoding GDNF to rats in order to evaluate the effect on damaged motor and sensory neurons (pgphs 641-704). Wherein in the cervical rhizotomy model, the expression of the transgene is mediated by injection of EIAV vectors pseudotyped with rabies envelope into the spinal cord. Retrograde transport of the vector allowed the expression of the vectors in the cell bodies of the DRG neurons (pgph 693). Wherein the vector may be administered intraperitonealy, intramuscularly, intravenously, intracranially or intratracheally (pgph 413). Wherein the vector may be used to treat Alzheimer's disease or stroke (pgph 167). Thus, by teaching all of the limitations of the claims as written, 2004/0266715 anticipates the instant invention as claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 7,8,10-14,17,18,20-24,27,28,30,32,34,38,42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10/838,906.

The claims of the instant application are drawn to a method for treating motor neuron disease comprising delivering a NOI to a target site, wherein the NOI is comprised within a lentiviral vector which is pseudotyped with a rabies G protein. Claims 1-7 of co-pending application 10/838,906 are drawn to a method for treating nerve injury in a mammal in need of such treatment, comprising administering a lentiviral vector pseudotyped with a rabies G protein, wherein the NOI encodes the RARβ2 protein. The method of co-pending application 10/838,906 is a species of the larger genus of the instantly claimed method.

It is well established that a species of a claimed invention renders the genus obvious. In re Schaumann , 572 F.2d 312, 197 USPQ 5 (CCPA 1978).

This is a provisional obviousness-type double patenting rejection.

No claims allowed.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0735. The fax phone number for the

organization where this application or proceeding is assigned is (571)-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Dr. Louis D. Lieto
Patent Examiner
Art Unit 1632

Deborah Crouch

DEBORAH CROUCH
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